



Economic and Social Council

Distr.: General
22 February 2018

Original: English

Economic Commission for Europe

Steering Committee on Trade Capacity and Standards

Fourth session

Geneva, 3-4 May 2018

Item 5 of the provisional agenda

Country follow-up to Economic Commission for Europe studies on regulatory and procedural barriers to trade

Regulatory and procedural barriers to trade: Evidence from Economic Commission for Europe national studies

Summary

This report highlights challenges to quality control and quality assurance development common to some Economic Commission for Europe (ECE) Member States. It draws on the results of the ECE's survey-based studies on regulatory and procedural barriers to trade in Albania, Kazakhstan, Kyrgyzstan, Moldova and Tajikistan.

An earlier draft of the report was presented to the 27th Session of the ECE Working Party on Regulatory Cooperation and Standardization Policies (WP.6) as part of the reference material to support discussions on setting up risk-based regulatory systems.

This report is presented to the Steering Committee on Trade Capacity and Standards for decision.

GE.18-02678(E)



• 1 8 0 2 6 7 8 •

Please recycle



I. Introduction

1. Several definitions have been advanced to conceptualize the notion of risk management and its implications for standard setting and legislative reforms.¹ The definitions bring forward the imperative for comprehensive risk-based approaches, which involve proactive consideration of foreseen and unforeseen events that could occur throughout the product life cycle to set the limits for achieving regulatory objectives. Such approaches should not only inform regulatory activities at both the planning and implementation levels, but also be integrated into the organizational, legislative and procedural processes underpinning the national system of standardization, technical regulations and quality assurance.²

2. There is no one size fits all solution, as each country has its specific conditions and development trajectory. This paper highlights major challenges that could complicate the institutionalizing risk-based regulatory systems, drawing on the findings of ECE studies on regulatory and procedural barriers to trade in Albania, Kazakhstan, Kyrgyzstan, the Republic of Moldova and Tajikistan.³

3. The paper is divided in five sections. The introduction is followed in sections two, three and four by an overview of the management systems underpinning standardization and quality assurance systems in the above-mentioned countries. The challenges facing regulatory bodies in the areas of technical regulations, standardization and conformity assessment are then discussed, leading to reflections on their policy implication.

II. Standardization and quality assurance systems: salient features

4. With the exception of Tajikistan, the general management of standardization and quality assurance systems in the five countries was assigned to line ministries responsible for the horizontal coordination of economic reforms, usually the Ministries of Economy, which worked closely with other relevant ministries and State agencies responsible for Veterinary, Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) measures (as shown in Table 1).

¹ See, for example, International Organization for Standardization (ISO) Guide 73:2009 (Risk Management -- Vocabulary).

² See, for example, ISO 31000:2009 (Risk Management--Principles and Guidelines), International Electrotechnical Commission (IEC) 31010:2009 (Risk Management--Risk Assessment Techniques), and, ISO/IEC 27001:2005 (Information Security--Security Techniques- Information Security Management Systems--Requirements). A summary of international standards and guides on risk management and their implication is provided in ECE (2012) Risk Management in Regulatory Frameworks: Towards a Better Management of Risks available at: http://www.unecce.org/fileadmin/DAM/trade/Publications/WP6_ECE_TRADE_390.pdf

³ The studies are available at: <https://www.unecce.org/tradewelcome/studies-on-regulatory-and-procedural-barriers-to-trade.html>. UNECE carried a similar study on Belarus in 2010. The paper does not cover Belarus, as the Government will be briefing the delegates on progress made in the area of risk management under agenda item 5.

Table 1. Agencies responsible for standardization and quality assurance oversight

Functions	Albania	Kazakhstan	Kyrgyzstan	Moldova	Tajikistan
Overall coordination	Ministry of Finance and Economy	Ministry of national Economy	Ministry of Economy	Ministry of Economy and Infrastructure	Ministry of Economic Development and Trade
Technical regulation	Line Ministries (sectoral regulations) and Ministry of Finance and Economy (horizontal regulations)	Line Ministries (sectoral regulations) and Ministry of national Economy (horizontal regulations)	Line Ministries (sectoral regulations) and Ministry of Economy (horizontal regulations)	Line Ministries (sectoral regulations) and Ministry of Economy and Infrastructure (horizontal regulations)	Tajikstandart
Standardization	General Directorate of Standardization (DPS)	Committee for Technical Regulation and Metrology (CTRM)	Centre for Standardization and Metrology	National Standardization Institute (NSI)	Tajikstandart
Conformity assessment	Independent conformity assessment bodies	Institute of Standardization and Certification (KazInSt)	Centre for Standardization and Metrology	Independent conformity assessment bodies	Tajikstandart
Accreditation	General Directorate of Accreditation (DPA)	National Accreditation Centre	Centre for Accreditation	National Accreditation Centre (MOLDAC)	Tajikstandart
Metrology	General Directorate of Metrology (DPM)	Kazakhstan Institute of Metrology (KazInMetr)	Centre for Standardization and Metrology	National Metrology Institute (NMI)	Tajikstandart
Market surveillance	Departments/ Inspectorates of branch ministries; Consumer Protection Commission; National Food Authority; Food Safety and Veterinary Institute; Market Surveillance Inspectorate; Consumer Associations	Territorial Departments of the CTRM; Departments/ Inspectorates of branch ministries	State Inspectorate of Environmental and Technical Safety; Departments/ Inspectorates of branch ministries	Consumer Protection Agency; National Food Safety Agency; Departments/ Inspectorates of branch ministries	Trade Inspection of Tajikstandart; Departments/ Inspectorates under line ministries

5. The development of the standardization and quality assurance systems was based on multi-year development plans, inspired by a drive to harmonize national legislation with the requirements of the multilateral trading system and those proper to main trading partners. The plans were geared to, among others, ensuring public safety; safeguarding the environment; promoting energy efficiency; improving competition; and, supporting regional and global integration.

6. Risk management was mainly addressed through regulatory impact assessments (RIA), which by virtue of focusing on the planning processes, did not allow for establishing a comprehensive risk management system.

7. Moreover, the specialized State agencies, including standard setting and conformity assessment bodies had limited revenue base, so that they were unable to invest in attracting and maintaining experts and/or, in the case of conformity assessment bodies, acquire modern laboratory equipment and supplies. All the agencies relied on the public purse for financing their running expenditures. Training, which all the agencies stressed as critical for improving their services, were mainly provided following a piece-meal approach within the context of donor-funded projects.

8. In the case of Tajikistan, the dominance of a single agency, namely Tajikstandart, caused conflicts of interests, which undermined the effectiveness of the entire system. Tajikstandart develops technical regulations, inspects, tests and then certifies products against these very same technical regulations. It also accredits conformity assessment bodies. The Government was taking steps to modernize the entire system so that the functions of standardization, conformity assessment, accreditation, metrology and market surveillance would be performed by independent agencies with specialized staff.

9. All of the reviewed countries reported effective cooperation with the international organizations. As shown in table 2, countries were at different stages of obtaining membership in regional and international organizations and of entering into the European Cooperation for Accreditation Multilateral Recognition Agreement (EA MLA) and the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement (ILAC MRA). However, given the above-mentioned capacity shortfalls, their membership in these organizations was elusive.

Table 2. Participation of the revised countries in the international/regional organizations

N	International/regional organizations	Albania	Kazakhstan	Kyrgyzstan	Moldova	Tajikistan
International organizations						
1	Organization for Standardization (ISO)	CM	FM	CM	CM	CM
2	International Organization of Legal Metrology (OIML)	FM	FM	n.a.m	CM	n.a.m
3	International Electrotechnical Commission (IEC)	AM	AM	n.a.m	AM	n.a.m
4	International Laboratory Accreditation Cooperation (ILAC)	FM	FM	FM	FM	n.a.m
	<i>International Laboratory Accreditation Cooperation</i>	S	S	S	S	n.y.a
	<i>Mutual Recognition Arrangement</i>					
5	Bureau International des Poids et Mesures (BIPM)	AM	FM	n.a.m	AM	n.a.m
6	International Accreditation Forum (IAF)	FM	FM	n.a.m	n.a.m	n.a.m
	<i>International Accreditation Forum Multilateral Recognition Arrangement</i>	n.y.a	S	n.y.a	n.y.a	n.y.a
7	International Measurement Confederation (IMEKO)	FM	FM	n.a.m	n.a.m	n.a.m

N	International/regional organizations	Albania	Kazakhstan	Kyrgyzstan	Moldova	Tajikistan
Regional organizations						
8	European Association of National Metrology Institutes (EURAMET)	FM	n.a.m	n.a.m	n.a.m	n.a.m
9	European Cooperation for Accreditation (EA)	FM	n.a.m	n.a.m	AM	n.a.m
	<i>European Cooperation for Accreditation Multilateral Recognition Agreement</i>	S	n.y.a	n.y.a	S	n.y.a
10	European Committee for Standardization (CEN)	AM	n.a.m	n.a.m	n.a.m	n.a.m
11	European Committee for Electrotechnical Standardization (CENELEC)	AM	n.a.m	n.a.m	n.a.m	n.a.m
12	CIS Inter-State Council for Standardization, Metrology and Certification (EASC)	n.a.m	FM	FM	FM	FM
13	Euro-Asian Cooperation of National Metrological Institutions (COOMET)	n.a.m	FM	FM	FM	FM

Legend: FM - full member; AM - associated member; CM - corresponding member; S - signatory; n.a.m - not a member; n.y.a - not yet admitted

III. Technical regulation

10. In all of the reviewed countries, technical regulations were elaborated by means of referencing to standards. This method involved mentioning only the essential safety requirements (or other requirements of the general interest) in the text of the legislative act, while listing the voluntary standards (which, when met, create a presumption of conformity). Driving technical regulation development were the countries' regional integration efforts, so that legislative approximation constituted the main reference framework for guiding decisions on technical regulations (Box 1).

11. The countries consider it as a good practice that the development of technical regulations is based on RIAs. RIAs are seen as a critical element for ensuring that regulatory requirements are well understood, that the benefits are greater than the costs, and that there are no alternative regulations for minimizing the costs assumed by enterprises. However, all the countries lacked the capacity to conduct rigorous RIAs due to the lack of qualified staff. For Albania and the Republic of Moldova, these capacity shortfalls came in addition to the recurrent government shuffles that have been disrupting the drafting process and generating high turnover rates. This has rendered a situation, whereby approximation took the form of transposing the translated corresponding EU directives into national law without proper adaptation.

Box 1. Regulatory harmonization in ECE region

In 2017, the Republic of Moldova was following ambitious plans⁴ to approximate the entire set of EU horizontal Directives⁵ along with 80 sectoral Directives.⁶

Members of the Eurasian Economic Union (EAEU) agreed to adopt common technical regulations for 61 products which were incorporated in the "Single List of Products". Existing national technical regulations for products were applicable until the entry of the common regulations into force.

12 In a cause-effect relation, the weaknesses in the decision-making process have set the limits to successful implementation. As shown in the remaining sections, there remained a gap in institutional capacities, both in terms methodologies for generating synergies between the different policy areas and in terms of the required procedures for implementing technical regulations. Hence, the double challenge for institutionalizing risk management in regulatory systems, as efforts have to take into account the capacity shortfalls in each area.

IV. Standardization

13 One of the main drivers for the modernization of the standardization system of the reviewed countries has been the accession to the WTO. For example, Tajikistan's authorities took the responsibility to dispense with mandatory standards by 2018.⁷ Regional integration efforts was another factor driving standardization policies and priority was given to harmonizing standards for export-oriented, import-substituting and innovative industries.

14 Consistent with international best practices,⁸ the standards were developed by technical committees. These were structured to ensure the broadest possible participation and create synergy with technical regulation development. Kyrgyzstan had 23 technical committees, Kazakhstan – 51 committees, Albania – 75 committees and the Republic of

⁴ See the National Action Plan for the Implementation of the Association Agreement (PNA AA) for 2014-2016 (approved by Governmental Decision No.808 of 7 October 2014 and amended by Decision No 713 of 12 October 2015) which spells out legislative and procedural reforms covering TBT provisions, and the Legislative Programme on implementing the commitments under the AA (Parliament Decision No.146 of 9 July 2015). In late 2016, the Government was preparing a new action plan on implementing Association Agreement for the period 2017-2019.

⁵ EU horizontal directives are established under the EU New Legislative Framework (NLF) for technical harmonization and standardization and the EU Directive 2001/95/EC on general product safety. The NLF principles and rules are set out under EC Regulation 765/2008 (for accreditation and market surveillance) and Decision 768/2008/EC (on a common framework for the marketing of products). EC Regulation 765/2008 and Decision 768/2008/EC are available at: http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

⁶ The EU sectoral directives define for each product group the essential health and safety requirements and the specific conformity assessment procedures to be followed.

⁷ Regulatory and Procedural Barriers to Trade in the Republic of Tajikistan: Needs Assessment – UNECE, 2014 – 114 p – P. 51.

⁸ See NSI Code of Best Practice (CBP 1-2) of 17 June 2014 on the "Principles and methodology of standardization. The structure and organization of technical standardization committees", which is based on international best practices as established under the provisions of the WTO Code of Good Practice (Annex 3 of the TBT Agreement), ISO/IEC Guide 59:1994 Code of Good Practice for Standardization and the CEN-CENELEC the Guide 20.

Moldova-18 committees. The committees brought together representatives from producers, traders, business and professional associations, research institutions, consumer associations, market surveillance authorities, testing laboratories, certification bodies and line Ministries, who worked under the guidance of an elected chair.

15. In practice, all of the countries were standard-takers and adopted harmonized standards as national standards through the cover sheet method. The main benefit of the standard-taker strategy is a quick modernization of local standards. However, this strategy generated significant risks for the local economy. One important consequence is that the international standards responded to the priorities of the developed countries. As such, they were more tuned with the realities of large companies rather than small and medium enterprises (SMEs) that dominated the economies of all the countries under review. This has meant that the enterprises were not ready to adequately respond to the rapid transformation of the national standards.

V. Conformity assessment (accreditation, product certification) and market surveillance

16. The conformity assessment systems of the reviewed countries were the subject of targeted reforms. In the case of Albania and the Republic of Moldova, reforms were geared towards institutionalizing the basic principles and rules established under the EU New Legislative Framework (NLF) for technical harmonization and standardization,⁹ including: the presumption of conformity, demarcation economic operators' responsibilities, protection of CE marking, designated procedures for conformity assessment, and, the separation of accreditation from other quality control and quality assurance functions.

17. The aim, as emphasized by interviewed officials, was to ensure adherence to safety and quality requirements throughout the product life cycle without creating unnecessary non-tariff barriers. This strategic goal also formed the focus of the remaining countries that were members of the EAEU.

18. However, conformity assessment results issued by national Conformity Assessment Bodies (CABs) were not recognized in the EU, as the accreditation agencies were yet to join the European Cooperation for Accreditation (EA) Multilateral Recognition Arrangement (MLA) and International Laboratory Accreditation Cooperation (ILAC) mutual recognition agreement (MRA). The signing of such agreements required strengthened the accreditation agencies, addressing capacity shortfalls within CABs, and, consolidating the country's market surveillance system.

19. Accreditation bodies operated under binding financial constraints, as Governments could not invest in improving their services, even as the costs were modest. This had been particularly the case with ILAC's peer assessments. Moreover, the majority of the existing CABs were publically owned, and, given the governments' budget constraints, were unable to invest in new testing laboratories.

20. Similarly, the Governments were unable to cover the costs for translating the guides and technical documents by specialized international organizations from English into national languages. For example, the Kyrgyz Centre for Accreditation (KCA) under the Ministry of Economy had only 3 staff, who were fluent in English, and while they were highly qualified lead assessors (1 for laboratories, 1 for certification and 1 for inspection

⁹ The NLF principles and rules are set out under EC Regulation 765/2008 (for accreditation and market surveillance) and Decision 768/2008/EC (on a common framework for the marketing of products). EC Regulation 765/2008 and Decision 768/2008/EC are available at: http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

bodies), they could not attend to the centre's translation needs. The centre was unable to attract qualified staff, since its salary scale was at par with that of the public sector, and could not generate enough income from fees. The fees for accrediting CABs, set at USD 1000 in 2015 by the Antimonopoly Authority, were too low to allow for achieving any degree of self-sufficiency.

21. As shown in box 2, mutual recognition agreements (MRAs) stood as the only mechanism for establishing cooperation arrangements with international trading partners. The TBT Agreement encourages members to enter into technical equivalence agreements (TEAs) with trading partners. These offer the most efficient tool for harmonization since they imply that products do not have to comply with the regulations of the importing country, assuming that the same objectives are fulfilled by the requirements of both countries. If establishing TEAs proves to be difficult, the Government considers establishing comprehensive mutual recognition agreements (MRAs), which cover several different industries and regulatory issues.

**Box 2. Examples of mutual recognition agreements
in the countries under review**

Albanian conformity assessment bodies have established cooperation agreements with their counterparts in Azerbaijan, Bosnia Herzegovina, Croatia, Czech Republic, Greece, FYROM, Kosovo, Montenegro, Poland, Romania, the Russian Federation, Sweden, Turkey.¹⁰

Kyrgyzstan had signed mutual recognition agreements with Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Moldova, China, Russia, Tajikistan, Turkmenistan, Ukraine and Uzbekistan.¹¹

The Republic of Moldova has established cooperation agreements in with Belarus, Bosnia and Herzegovina, Cyprus, Czech Republic, Estonia, Kazakhstan, Kyrgyzstan, Macedonia, Poland, Romania, Slovakia, Turkey and Ukraine.¹²

22. Countries attached great importance to developing effective market surveillance systems. However, these systems were developed in the absence of a coherent risk based strategy. For example, the establishment a market surveillance system was guided by the National Strategy on Consumer Protection and Market Surveillance for the period 2014-2020. The strategy emphasized the urgent need for: establishing a national database of non-food products; developing adequate information and communication technology infrastructure for supporting information exchange between different market surveillance agencies; and, for implementing a risk classification and assessment methodology. These capacity shortfalls were seen as impeding the country's participation in the EU Rapid Alert System for dangerous non-food products (RAPEX) and the Information and Communication System for Market Surveillance (ICSMS).¹³

23. The strategy did not contain a risk assessment methodology; policy statement on the principles underpinning market surveillance activities; and, internal guidelines defining the scope of interagency coordination and procedures for facilitating such coordination. Complementary measures were also needed, including food traceability systems.

¹⁰ Regulatory and Procedural Barriers to Trade in Albania: Needs Assessment / UNECE, 2016. – 149 p. – P. 87.

¹¹ Regulatory and Procedural Barriers to Trade in the Republic of Kyrgyzstan: Needs Assessment / UNECE, 2015. – 230 p. – P. 105.

¹² Regulatory and Procedural Barriers to Trade in the Republic of Moldova: Needs Assessment / UNECE, 2017. – 196 p. – P. 62.

¹³ Regulatory and Procedural Barriers to Trade in Albania: Needs Assessment / UNECE, 2016. – 149 p. – P. 101-102.

24. Other countries adopted an incremental approach to developing the market surveillance system, focusing on priority products with high export potential. This was the case of Kyrgyzstan, which applied a progressive approach in the inspection activities of the

Box 3. An incremental approach to market surveillance systems: the experience of Kyrgyzstan

SIETS inspections are carried out within the context of risk-based planning, and enterprises could address their inquiries to SIETS through a hotline. Inspection plans are prepared based on risk assessments, and submitted to the Ministry of Economy for approval one year in advance. Enterprises that are assessed as posing a high risk (due to shortfalls in the equipment, product, technology and works) are inspected once a year. Enterprises with medium risk levels are inspected once every three years, while those with low risk levels are inspected once every five years.¹⁴

State Inspectorate of Environmental and Technical Safety (SIETS), as seen in box 3.

VI. Policy implication

25. The evidence emerging from ECE studies show that establishing risk based management systems for guiding standardisation and quality assurance functions is a challenging undertaking. The countries under review lacked the required rulemaking, conformity assessment, and accreditation capacities to detect and address foreseen and unforeseen risks that may deter the achievement of regulatory objectives throughout the product life cycle.

26. The evidence also suggests that establishing risk based systems will not automatically translate into increased and diversified exports. Compliance with safety and quality regulatory requirements often involves investments in specialized production technologies and expensive equipment, which may not be available locally. For the majority of the enterprises in the reviewed countries, where comparative advantage lies in maintaining low capital costs and high labour inputs, even relatively small additional investments in equipment could overstretch available short-term credit limits and result in substantial increases to marginal costs.

27. Moreover, the required equipment or management expertise is not always available locally, and the enterprises lack the capacity to conduct international searches for suitable suppliers. Even where equipment and related auxiliary services were available locally, they were often more expensive than imports. Thus, for enterprises the costs of compliance are likely to be higher than for competitors in developed countries. With the list of environmental, health and safety standards and technical regulations continuously expanding to reflect the complexities of international supply chains, the traders are likely to face worsening market access conditions in regional and global markets.

28. These fundamental requirements should be addressed as the governments forge ahead in establishing risk based systems.

¹⁴ Regulatory and Procedural Barriers to Trade in the Republic of Kyrgyzstan: Needs Assessment UNECE, 2015 – 230 p. – P. 108.